

### **REMARKS**

These remarks are in response to the Office Action dated February 7, 1997. As stated in the Office Action, Paper 5, paragraph 4, Applicant's representative had provisionally elected with traverse to prosecute Claims 1 and 4. Applicant hereby affirms this election. Claims 2, 3, 5 and 6 are therefore withdrawn from consideration. Claims 1 and 4 have been canceled without prejudice. No new matter has been added. Claims 7-12 have been added to better define the claimed invention. Support for these claims can be found throughout the specification. Applicant respectfully requests reconsideration of the present application.

### **THE INVENTION**

The invention provides kits for screening for recombinant enzymes expressed by DNA libraries. A plurality of expressed recombinant enzymes are characterized by common chemical and physical characteristics.

#### **I. REJECTIONS UNDER 35 U.S.C. §112**

Claims 1 and 4 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to provide enablement for any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicant notes that this rejection is moot with respect to canceled claims 1 and 4. Applicant respectfully traverses this rejection as it may apply to new claims 7-12.

Specifically, the Examiner alleges that the specification does not reasonably provide enablement for kits comprising enzymes isolated by the disclosed screening methods. However, the Examiner states on page 4, line 12, of the Office Action, that the specification is enabling for enzyme kits comprising enzymes isolated by conventional means.

The claimed invention provides a kit containing at least one, and preferably more than one, enzymatic activities previously identified by screening recombinant expression vectors for said activities. A kit is provided such that the enzymatic activities are grouped in what are described in the originally filed patent application as "Tiers". For example, a kit comprised of Tier 1 enzymes will contain activities selected from the group consisting of oxidoreductase, transferase, hydrolase, lyase, isomerase and ligase. Therefore, the present invention provides a starting point from which subsequent analysis of enzymatic activities can occur, ultimately resulting in the identification of novel enzymes.

The Examiner states on page 5, lines 17-19, of the Office Action, that "the amount of experimentation in subsequent tiers is enormous because of the tremendous number of possible specific substrates that may be necessary to hone in on the specific activity of any given enzyme." The Examiner further states on page 5, lines 19-20, bridging to page 6, line 1, of the Office Action that "While recombinant screening techniques are available, it is not routine in the art to screen large numbers of possible substrates where the expectation of detecting and obtaining enzymes with particular activities /functions is unpredictable based on the instant disclosure." Applicant submits, and the courts agree, that the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. Those skilled in the art of enzymology routinely screen vast numbers enzymes displaying various activities for the purposes of identifying and characterizing novel activities. Further, the advent of automated screening techniques has augmented the ability of the skilled artisan to isolate such activities from a sample containing many similar and dissimilar activities. The present invention enables those skilled in the art to begin a search for a particular activity with a subset of activities already identified as, for example, in the case of a Tier 1 kit, a hydrolase. Moreover, Applicant believes that skilled artisans familiar with such activities will utilize substrates necessary to further identify enzymes displaying specific hydrolase activities. Applicant further believes that it should not be incumbent upon the claimed invention to provide every possible substrate for every possible enzymatic activity that may or may not be contained in the claimed invention.

Therefore, Applicant believes that the amount of experimentation left to those skilled in the art is not undue in light of the guidance disclosed in the specification, the presence of working examples and the state of the prior art. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

## **II. REJECTIONS UNDER 35 U.S.C. §102**

Claims 1 and 4 stand rejected under 35 U.S.C. §102 (b) as allegedly anticipated by GibcoBRL. Applicant notes that this rejection is moot with respect to canceled claims 1 and 4. Applicant respectfully traverses this rejection as it may apply to new claims 7-12.

“Anticipation requires the disclosure in a single prior art reference of each element in the claim under consideration.” In re Spada, 15 USPQ 2d 1655 (Fed. Cir., 1990), In re Bond 15 USPQ 2d 1566 (Fed. Cir., 1990).

As previously noted, claims 7-11 have been added to more clearly identify that which the Applicant believes is the claimed invention. Further, the cited reference teaches a kit containing purified enzymes for the purpose of cDNA synthesis. In contrast, the kit of the claimed invention contains compositions of enzymatic activities broadly characterized, for example, by the IUB class in which the activity is categorized. As previously stated, the present invention provides a starting point for the further analysis and subsequent identification of novel enzymatic activities. The present invention is not intended to provide purified enzymes for the purpose of synthesizing cDNA, as is the case for the cited reference. Therefore, Applicant submits that the cited reference does not teach each and every element of the claimed invention and respectfully argues that the kit of the claimed invention is not anticipated by the reference cited by the Examiner.

Accordingly, Applicant respectfully requests that this rejection under 35 U.S.C. §102 be withdrawn.

In summary, for the reasons set forth herein, Applicant maintains that claims 7-12 clearly and patentably define the invention, respectfully requests that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully requests the allowance of the claim which is now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (619) 678-5070.

Please charge any additional fees, or make any credits, to Deposit Account No. 06-1050.

Respectfully submitted,

Date:

7/7/97



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